OCT - 1 2001

510(K) SUMMARY

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

COLORED(Green)POWDER FREE LATEX EXAMINATIN GLOVES WITH ALOE VERA AND PROTEIN LABELING CLAIM(50 MICROGRAM OR LESS PER GRAM OF GLOVE)

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, and prepared on July 25, 2001

The assigned 510(K) number is K012709

1.0 Submitter:

Qingdao Bestex Rubber & Plastic Products Co. Ltd.
14-2 Hangzhou Road,
Pingdu., Qingdao, China

2.0 Regulatory Affairs Contact:

Name: ZeChuan Shao
Phone No.: 408 980 1348
Fax No.: 408 980 1356

3.0 Name of device:

Trade Name: Undetermined
Common Name: Examination Glove
Classification Name: Patient Examination Glove, Powder Free

4.0 Identification of The Legally Marketed Device:

Class I patient examination gloves, 80LYY, non-sterile, powder free with aloe vera, that meets all the requirements of ASTM standard 3578-00 and FDA 21 CFR 800.20.

5.0 Device Description:

Class I powder free colored(green) latex examination gloves with aloe vera and protein labeling claim(50 microgram or less) ,80LYY, non-sterile meets all the requirements of ASTM standard D3578-00 and FDA 21 CFR 800.20.

6.0 Intended Use of The Device:

The powder free colored latex examination glove with aloe vera and protein labeling claim(50 microgram or less) is a disposable device made of natural rubber latex that may bear a trace amount of glove powder and is intended for medical purposes that are worn on the examiner's hands or fingers to provide a barrier against potentially infectious materials and other contaminants.

7.0 Summary of the Technological Characteristics of the Device:

The Powder Free Colored Latex Examination Gloves with Aloe Vera and with Protein Content Labeling(50 micrograms or less) are summarized with the following technological characteristics compared to ASTM or equivalent standards:

Characteristics	Standards	Device Performance
Dimensions	ASTM D 3578-00	Meets
Physical Properties	ASTM D 3578-00	Meets
Freedom from Pinholes	ASTM D 3578-00 FDA 21 CFR 800.20	Meets Meets
Powder Free	ASTM D 6124-97	<2 mg/glove
Protein Level	ASTM D5712-95	<50 microgram/gram
Biocompatability	Primary Skin Irritation In Rabbits	Passes(not a primary skin irritant)
	Dermal Sensitization	Passes(Not a contact sensitizer)

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The standards used by Bestex Rubber & Plastic Products Co., Ltd. to determine substantial equivalence are based on ASTM 3578-00 AND FDA 21 CFR 800.20. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0, Pinholes at AQL 1.5

Primary Skin Irritation and Skin Sensitization testing were also conducted with results showing no primary sin irritation or sensitization reactions, meets all performance and biocompatibility requirements.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

No new clinical test were conducted under this 510(K)

10.0 Other Information Deemed Necessary by FDA:

Not applicable.

Conclusion

The data presented indicate that the Powder Free Colored Latex Examination Glove with Aloe Vera and with a protein labeling claim(50 microgram or less) meets ASTM standards, meet FDA pinhole requirements , biocompatibility requirements, and labeling claims. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Qingdao Bestex Rubber & Plastic Products Company Limited
C/O Mr. Zechuan Shao
General Manager
2576 Lafayette Street
Santa Clara, California 95050

Re: K012709
Trade/Device Name: Powder Free Latex Examination Gloves with Aloe Vera and Protein Content Labeling Claim (50 Micrograms or Less) (Green)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: July 25, 2001
Received: August 14, 2001

Dear Mr. Shao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not

mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

Applicant: Qingdao Bestex Rubber & Plastic Co. , Ltd.

510(k) Number (if known): K012709

Device Name: Powder-Free Latex Examination Glove Colored, with Aloe Vera and Protein Content Labeling Claim (50 micrograms or less) (GREEN)

Indications For Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. (21CFR 880.6250)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Qian S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012709

Prescription Use_____ OR Over-The-Counter _____
Per 21 CFR 801.109 (Optional Format 1-2-96)